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DRAFT SAP white paper\_OCSP management review.docx

Stephanie, Mike, and Kristine,

Attached please find our current draft SAP whitepaper that is going through management review at this time. As part of our evaluation of the genotoxicity study, we incorporated many of the things we discussed over the phone last week. If you have any suggestions on how to improve the genotoxicity evaluations section, we would greatly appreciate it, including some of the more specific deficiencies you noted in your review that were not captured in the write-up. We will be submitting the final draft for the SAP in mid-September.

Again, thank you for taking time to discuss with us last week. It was extremely helpful!

-Monique

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